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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,874	02/08/2001	Michael Wassenegger	MPG-1 DIV-1	6565

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1633	7

DATE MAILED: 01/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/782,874	Applicant(s) WASSENEGGER ET AL.	
	Examiner Michael Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 13-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 13-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 2-6-01 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Claims 1-61 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 53-61 drawn to nucleic acids, vectors, hosts and methods of expression, classifiable in class 435, subclasses 325 and 320.1.

II. Claims 13, 14, 17, 18, 49, drawn to proteins, classifiable in class 435, subclass 183.

III. Claim 15, drawn to antibody and methods of its use, classifiable in class 530, subclass 387.1.

IV. Claims 16 and 50, drawn to antagonists and inhibitors, classifiable in class 514, subclass 4.

V. Claims 22-26, drawn to methods of treatment, classifiable in class 514, subclass 14.

VI. Claims 27, 28, 42, 43, drawn to transgenic animals, classifiable in class 800, subclass 8.

VII. Claims 44-46, drawn to transgenic cells, classifiable in class 435, subclass 325.

VIII. Claims 29-38, drawn to transgenic plants, plant cells, and plant tissue culture, classifiable in class 800, subclass 295.

IX. Claims 40, 41, drawn to transgenic organisms, classifiable in class 800, subclasses 8 and 295.

X. Claim 50, drawn to inhibition of gene expression using antisense, classifiable in class 514, subclass 44.

XI. Claim 52, drawn to inhibition of gene expression using knockout constructs, classified in various classes and subclasses.

Claims 19-21 and 39 are generic to each of groups I and II. Should any one of groups I and II be elected, claims 19-21 and 39 will be examined to the extent that they encompass the elected subject matter.

Claims 19 and 20 are generic to each of groups III and IV. Should any one of groups III and IV be elected, claims 19 and 20 will be examined to the extent that they encompass the elected subject matter.

Claim 47 is generic to each of groups VI and VII. Should any one of groups VI and VII be elected, claim 47 will be examined to the extent that it encompasses the elected subject matter.

Claim 48 is generic to each of groups VI and VIII. Should any one of groups VI and VIII be elected, claim 48 will be examined to the extent that it encompasses the elected subject matter.

Claim 51 is generic to each of groups III and IV (as the nucleic acid and vector claims have been canceled). Should Group III or IV be elected, claim 51 will be examined to the extent that it encompasses the elected subject matter.

Should group V be elected, a further election of species is required. Group V is generic to a plurality of disclosed patentably distinct species comprising animals and plants. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either

instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should group IX be elected, a further election of species is required. Group IX is generic to a plurality of disclosed patentably distinct species comprising animals and plants. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions of group I are patentably different from the inventions of groups II because inventions of group I are drawn to nucleic acid molecules and vectors thereof, host cells harboring said nucleic acids and methods of expression of said vectors in said host cells, whereas inventions of group II are drawn to proteins and method of using and assaying said proteins. Inventions of group I are also patentably different from the inventions of groups III and group IV because inventions of group III are drawn to antibody while inventions of group IV are drawn to antagonist and inhibitors and methods of identifying such molecules.

Inventions of group I are also patentably different from the inventions of groups V and VI because inventions of group V are drawn to methods of treatment whereas the inventions of group VI are drawn to transgenic animals and methods of producing transgenic animals.

Inventions of group I are also patentably different from the inventions of groups VII and VIII because inventions of group VII are directed to transgenic cells while the inventions of group VIII are drawn to transgenic plants, plant cells and plant tissues thereof.

Inventions of group I are patentably different from the inventions of groups IX and X because inventions of group IX are drawn to transgenic organisms while the inventions of group X and XI are drawn to inhibition of gene expression using nucleic acids.

There is nothing on the record to suggest that the inventions are obvious variants.

As stated above, inventions of different group are patentably distinct from each other because their analysis will require different search strategies which are not coextensive. For example, inventions of group I will require search of vectors, host cells, nucleic acid molecules and methods thereof which will be different for the search required for the analysis of inventions of group II which will require search of proteins, enzymes, and methods of enzyme assay. Similarly, the analysis strategy for the inventions of group III will be distinct from those used for group I and II, because it will require search for antibody, methods of use and assay of antibody-antigen binding which will be different than those for vector, host cells, nucleic acid or enzymes. Additionally, the inventions of each of the Group I-III are distinct from each other because they are drawn to compositions having materially different chemical structures, physical properties and utilities, and requiring separate searches. Furthermore, there is nothing on record to indicate that the compositions are obvious variants.

The analysis of the inventions of the group IV will be different from the rest of the groups because it will require search for antagonists and inhibitors of enzyme and methods of identifying such molecules and such a analysis will be different compared to the strategy describe above for the groups I-III. Likewise the search and analysis strategy for inventions of

group V will require search for methods of nucleic acid and protein delivery to organisms and cells and therefore will be clearly different from the search criteria used for groups I-IV.

The analysis of inventions of group VI will require considerations of transgenic animals and methods of making transgenic animals which encompasses issues such as animal species, and methods of nucleic acid introduction in the germ line, and therefore the search and analysis strategy will be different from those employed for other groups. The inventions of the groups VII and VIII are different from the inventions of other groups, because analysis of claims of group VII will require considerations of regulatory elements required for transcription in a transgenic mammalian cell and effects thereof on polypeptide synthesis.

The inventions of group VIII, on the other hand, will require the search considerations of transgenic plants, plant cells, plant tissue culture which is materially different from search considerations of transgenic animal cells. The inventions of groups IX and X or XI will also require analysis strategies distinct from each other as well as from other groups because the claims of group IX are drawn to transgenic organisms, antagonists and inhibition and heterologous gene expression. On the other hand, the analysis of inventions of group X or XI will require considerations of inhibitory mechanisms of host cells by nucleic acids and proteins, which is distinct from those used for other groups. Groups X and XI are patentably distinct because antisense and knockout construct have different modes of operation, are structurally different and require a different search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Furthermore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.